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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,189	09/21/2006	Alexei Shir	29770	5260

67801 7590 05/27/2009

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
05/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,189	SHIR ET AL.	
	Examiner	Art Unit	
	TERRA C. GIBBS	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *96-99 and 103-114* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *96-99 and 103-114* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission mailed on March 18, 2009 has been entered.

Claims 100-102 have been canceled. New claims 110-114 are acknowledged. Claims 96, 105, and 106 have been amended.

Claims 96-99 and 103-114 are pending in the instant application.

Claims 96-99 and 103-114 been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Applicant's Amendment and Response mailed March 18, 2009 have been considered. Rejections and/or objections not reiterated from the previous Office Action mailed November 26, 2008 are hereby withdrawn. Any arguments addressing said rejections and/or objections are moot. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Claim Rejections - 35 USC § 102

In the previous Office Action mailed November 26, 2008, claims 96-98 were rejected under 35 U.S.C. 102(a) as being anticipated by Abounader et al. (The FASEB Journal, 2002 Jan;16(1):108-10. Epub 2001 Nov 29). **This rejection is withdrawn** in view of Applicant's Amendment filed March 18, 2009. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to the claims to recite a method of using a double stranded RNA molecule which induces viral-like double stranded mediated apoptosis, triggered by upregulation of interferon (IFN)-α/β expression. It is noted that Abounader et al. teach a method of using a ribozyme, where it is known in the art that ribozymes do not induce viral-like double stranded mediated apoptosis, triggered by upregulation of interferon (IFN)-α/β expression.

In the previous Office Action mailed November 26, 2008, claims 96-98 were rejected under 35 U.S.C. 102(b) as being anticipated by Czubayko et al. (Proc. Natl. Acad. Sci., 1996 Vol. 93:14753-14758). **This rejection is withdrawn** in view of Applicant's Amendment filed March 18, 2009. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to the claims to recite a method of using a double stranded RNA molecule which induces viral-like double stranded mediated apoptosis, triggered by upregulation of interferon (IFN)-α/β expression. It is noted that Czubayko et al. teach a method of using a ribozyme, where it is known in the art that ribozymes do not induce viral-like double stranded mediated apoptosis, triggered by upregulation of interferon (IFN)-α/β expression.

In the previous Office Action mailed November 26, 2008, claims 96-98 were rejected under 35 U.S.C. 102(b) as being anticipated by Zhao et al. (Development, 1998 Vol. 125:1899-1907). **This rejection is withdrawn** in view of Applicant's Amendment filed March 18, 2009. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to the claims to recite a method of using a double stranded RNA molecule which induces viral-like double stranded mediated apoptosis, triggered by upregulation of interferon (IFN)-α/β expression. It is noted that Zhao et al. teach a method of using a ribozyme, where it is known in the art that ribozymes do not induce viral-like double stranded mediated apoptosis, triggered by upregulation of interferon (IFN)-α/β expression.

Claim Rejections - 35 USC § 103

In the previous Office Action mailed, December 27, 2007, claims 96-109 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/23050 (submitted on Applicant's Information Disclosure Statement filed February 7, 2007) in view of Yamazaki et al. (Journal of the National Cancer Institute, 1998 Vol. 90:581-587) and Ogris et al. (Journal of Biological Chemistry, 2001 Vol. 276:47550-47555). **This rejection is moot** against claims 100-102 in view of Applicant's Amendment filed March 18, 2009 to cancel these claims. **This rejection is withdrawn against the remaining claims** in view of Applicant's Amendment filed March 18, 2009. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to the claims to recite a method of using a double stranded RNA molecule which induces viral-like

double stranded mediated apoptosis, triggered by upregulation of interferon (IFN)-α/β expression. It is noted that none of the cited art teaches a method of using a double stranded RNA molecule which induces viral-like double stranded mediated apoptosis, triggered by upregulation of interferon (IFN)-α/β expression.

After careful reconsideration of the application and claims, a new grounds of rejection(s) is made of record as presented below:

Information Disclosure Statement

Applicant's Information Disclosure Statement (IDS) filed February 7, 2007 is acknowledged. It is also acknowledged that the Examiner considered the Information Disclosure Statement filed February 7, 2007. However, after reconsideration of the IDS, the Examiner noted that reference #6 (Shir et al. "Efficient Killing of Glioblastoma and Other Cancers by Cancer Specific Transfection of dsRNA") lacks a publication date or reference source (i.e. journal name, book name, etc.). To maintain the integrity of the record, Applicants are requested to provide the publication date, reference source, volume number, page number(s), and any other pertinent information regarding reference #6.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 114 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 114 is indefinite because the term, "EGF" is not clearly defined. Since abbreviations often have more than one meaning, it is suggested that inserting the full name of the growth factor would overcome the instant rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 96-99 and 103-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/23050 (submitted on Applicant's Information Disclosure Statement filed February 7, 2007), in view of Yamazaki et al. (Journal of the National Cancer Institute, 1998 Vol. 90:581-587, of record), Farrell et al. (submitted on Applicant's Information Disclosure Statement filed February 7, 2007), and Ogris et al. (Journal of Biological Chemistry, 2001 Vol. 276:47550-47555, of record).

Claim 96 is drawn to a method of killing a specific target cell and/or tissue, the method comprising exposing the specific target cell and/or tissue to a composition-of-matter comprising (i) a double stranded RNA molecule, said molecule consisting of 2 RNA strands which induces viral-like double stranded mediated apoptosis, triggered by upregulation of interferon (IFN)-α/β expression in said cell and/or tissue; (ii) a nucleic acid carrier; and (iii) a targeting moiety, said targeting moiety being a ligand or antibody which binds to a cell surface marker being specific to the target cell and/or tissue; said double stranded RNA molecule is associated with said nucleic acid carrier, said nucleic acid carrier is associated with said targeting moiety and said targeting moiety is not covalently bound to said double stranded RNA molecule, and further wherein said double stranded RNA, said targeting moiety, and said nucleic acid carrier form a particle which penetrates solid tumor tissue, thereby killing the specific target cell and/or tissue. Claims 97-99 and 103-114 are dependent on claim 96 and includes all the limitations of claim 96 with the further limitations wherein said exposing the specific target cell and/or

tissue to said composition-of-matter is effected by administering said composition-of-matter to a vertebrate subject bearing the specific target cell and/or tissue; wherein said administering said composition-of-matter to said vertebrate subject is effected by administering said composition-of-matter to said subject systemically and/or to a central nervous system location of said vertebrate subject; wherein said composition-of-matter further comprises melittin; wherein said targeting moiety is a ligand of a surface marker of said specific cell and/or tissue; wherein said ligand of said surface marker is a biological ligand of said surface marker; wherein said targeting moiety is an antibody or antibody fragment; wherein said targeting moiety is a growth factor; wherein said growth factor is epidermal growth factor; wherein said surface marker is a growth factor receptor; wherein said surface marker is epidermal growth factor receptor; wherein said double stranded RNA comprises a polyinosinic acid stand and/or a polycytidylic acid strand; wherein said nucleic acid carrier comprises a biocompatible polymer; wherein said polymer is PEI or PEG; wherein said double stranded RNA molecule is wholly composed of matching ribonucleotide pairs; wherein said double stranded RNA molecule comprises mismatched ribonucleotide pairs on average less than one base pair in every 29 consecutive base residues; wherein a ratio of said double stranded RNA molecule, said nucleic acid carrier, said melittin is selected such that at a concentration of 10 μg/ml the composition is capable of selectively killing more than 95% of glioblastoma cells 24 hours following transfection as measured in an *in vitro* assay; wherein said carrier is covalently associated with said targeting moiety.

It is noted that Applicant's specification, at page 45, Background discloses:

"While various prior art approaches have attempted to use dsRNA for selectively killing cells displaying a specific surface marker, all such approaches suffer from various critical disadvantages, including suboptimal efficacy, safety, and/or selectivity".

Determining the scope and contents of the prior art

WO 94/23050 teaches:

A method of blocking translation of an RNA transcript in a cell or an organism, comprising administering to an organism a soluble molecular complex comprising an expressible gene encoding an RNA which hybridizes to and inhibits the function of a cellular RNA, the RNA being complexed with a carrier comprising a cell-specific binding agent and a gene-binding agent (see Abstract and claim 20, for example).

WO 94/23050 teaches that the gene encoding an RNA is an antisense, wherein the antisense can be in the form of small, chemically synthesized DNA or RNA oligonucleotides, or can be larger RNAs (see page 1, second paragraph, for example).

WO 94/23050 teaches that the molecular complexes of their invention comprise an expressible gene encoding a desired polyribonucleotide (e.g. antisense) complexed to a carrier which is a conjugate of a cell-specific binding agent and a gene-binding agent (see page 1, last paragraph). WO 94/23050 teaches that the binding agent is an antibody (see page 3, lines 21 and 22) and the gene-binding agent is a polycation, for example (see page 4, first full paragraph). WO 94/23050 teaches that the carrier of their invention can be formed by chemically linking the cell-specific binding agent and the gene-binding agent; wherein the linkage is a peptide or disulfide bond, for example. WO 94/23050 also teaches that a noncovalent bond based on electrostatic attraction between the gene-binding agent and the expressible gene provides extracellular stability and is releasable under intracellular conditions (see page 4).

WO 94/23050 teaches the cell-specific binding agent is specific for a cellular surface structure which mediates internalization of ligands by endocytosis and the gene-binding agent is a compound such as a polycation which stably complexes the gene under extracellular conditions and releases the gene under intracellular conditions so that it can function within a cell.

> WO 94/23050 teaches that the molecular complex of their invention is stable and soluble in physiological fluids and can be used in antisense gene therapy to selectively transfect cells *in vivo* (see Abstract). WO 94/23050 also teaches that the molecular complex of their invention is adaptable for delivery of a wide range of genes to a specific cell or tissue (see page 6, first full paragraph).
>
> WO 94/23050 teaches that the ratio for a particular polynucleotide and carrier can be determined by methods well-known in the art (see page 5, first full paragraph).
>
> WO 94/23050 also teaches and claims that the antisense RNA used in the method of their claimed invention (claim 20) is a ribozyme (see claim 28).

Yamazaki et al. teach a method of inhibiting cellular growth and killing tumor cells, the method comprising administering a double stranded RNA ribozyme (see Figure 1); a nucleic acid carrier (see vector used for *in vivo* delivery); and a targeting moiety (regions of complementary sequence in Figure 1). It is noted that the double stranded RNA molecule is associated with the nucleic acid carrier by ligation/annealing and the nucleic acid carrier is associated with the targeting moiety by ligation/annealing. It is further noted that Applicants have not defined the term "targeting moiety". Applicant is reminded that during patent examination, the claims are given the broadest reasonable interpretation consistent with the specification. See MPEP § 2111-2116.01. Given its broadest reasonable interpretation, the Examiner has interpreted the term “targeting moiety” to include the regions of complementary sequence in Figure 1, where those tumor cells expressing the target are selectively killed.

Yamazaki et al. also teach that the dsRNA ribozyme is a epidermal growth factor receptor (EGFR) that targets aberrant EGFR substrates and transcripts (see Abstract).

Ascertaining the differences between the prior art and the claims at issue

Neither WO 94/23050 nor Yamazaki et al. teach a double stranded RNA molecule, said molecule consisting of 2 RNA strands which induces viral-like double stranded mediated apoptosis, triggered by upregulation of interferon (IFN)-α/β expression. Additionally, neither WO 94/23050 nor Yamazaki et al. teach wherein the composition-of-matter further comprises melittin or wherein the nucleic acid carrier comprises a biocompatible polymer, including PEI or PEG.

Farrell et al. teach double stranded RNA molecules consisting of 2 RNA strands which are triggered by upregulation of interferon (IFN)-α/β expression (see Figure 1). Farrell et al. teach that the double stranded RNA molecules consisting of 2 RNA strands which are triggered by upregulation of interferon (IFN)-α/β expression impair and inhibit protein synthesis (see Abstract, for example).

Ogris et al. teach that melittin, a cationic membrane-active short peptide enables efficient vesicular assess of gene delivery vectors (see Abstract). Specifically, Ogris et al. teach that melittin-PEI•DNA complexes exhibit higher transfection efficiency than PEI/DNA complexes alone (see Figures).

Resolving the level of ordinary skill in the pertinent art

The level of ordinary skill in the pertinent art is considered to be high, being a graduate student or post-doctoral fellow in a biological science.

Considering objective evidence present in the application indicating obviousness or nonobviousness

It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made to devise a method of killing a specific target cell and/or tissue, the method comprising exposing the specific target cell and/or tissue to a

composition-of-matter comprising (i) a double stranded RNA molecule (ii) a nucleic acid carrier; and (iii) a targeting moiety using the teachings of WO 94/23050 or Yamazaki et al. It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made to have the double stranded RNA molecule consist of 2 RNA strands which induce viral-like double stranded mediated apoptosis, triggered by upregulation of interferon (IFN)-α/β expression using the teachings of Farrell et al. It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made to have the composition-of-matter further comprises melittin using the teachings of Ogris et al. It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made to have the nucleic acid carrier comprise PEI using the teachings of Ogris et al.

One of ordinary skill in the art would have been motivated to devise a method of killing a specific target cell and/or tissue, the method comprising exposing the specific target cell and/or tissue to a composition-of-matter comprising (i) a double stranded RNA molecule (ii) a nucleic acid carrier; and (iii) a targeting moiety because WO 94/23050 and Yamazaki et al. taught such a method could inhibit the growth of tumors *in vivo*.

Furthermore, one of ordinary skill in the art would have been motivated to devise a method of killing a specific target cell and/or tissue, the method comprising exposing the specific target cell and/or tissue to a composition-of-matter comprising a double stranded RNA molecule since, afterall, Applicant's specification teaches various prior art approaches have attempted to use dsRNA for selectively killing cells displaying a

specific surface marker (see page 45).

One of ordinary skill in the art would have been motivated to substitute the double stranded RNA molecule of WO 94/23050 or Yamazaki et al. with a double stranded RNA molecule consisting of 2 RNA strands which induces viral-like double stranded mediated apoptosis, triggered by upregulation of interferon (IFN)-α/β expression since both molecules kills a specific target cell and/or tissue and one would be motivated to substitute one functional equivalent for another, particularly when they are to be used for the same purpose. See MPEP 2144.06.

One of ordinary skill in the art would have been motivated to have the composition-of-matter further comprise melittin and to have the nucleic acid carrier comprise PEI because Ogris et al. taught that melittin-PEI•DNA complexes are great candidates for systemic gene delivery *in vivo*.

One of ordinary skill in the art would have had a reasonable expectation of success of devising a method of killing a specific target cell and/or tissue, the method comprising exposing the specific target cell and/or tissue to a composition-of-matter comprising (i) a double stranded RNA molecule (ii) a nucleic acid carrier; and (iii) a targeting moiety since Yamazaki et al. taught the successful use and design of such a method to inhibit tumor growth in mice.

One of ordinary skill in the art would have had a reasonable expectation of substituting the double stranded RNA molecule of WO 94/23050 or Yamazaki et al. with a double stranded RNA molecule consisting of 2 RNA strands which induces viral-like double stranded mediated apoptosis, triggered by upregulation of interferon (IFN)-

α/β expression because KSR forecloses that the simple substitution of one known element for another would have yielded predictable results at the time of the invention. See recent U.S. Supreme Court decision in the KSR International v. Teleflex Inc. (82 USPQ2d 1385).

Furthermore, one of ordinary skill in the art would have had a reasonable expectation of substituting the double stranded RNA molecule of WO 94/23050 with a double stranded RNA molecule consisting of 2 RNA strands which induces viral-like double stranded mediated apoptosis, triggered by upregulation of interferon because WO 94/23050 teaches at page 9, last paragraph:

> **"Those skilled in the art will recognize, or be able to ascertain using no more than routine experimentation, numerous equivalents to the specific procedures described herein. Such equivalents are considered to be within the scope of the invention".**

One of ordinary skill in the art would have had a reasonable expectation of success of having the composition-of-matter further comprises melittin since Ogris et al. taught the successful use and delivery of melittin and DNA complexes to a whole animal. One of ordinary skill in the art would have had a reasonable expectation of success of having the nucleic acid carrier comprise PEI since Ogris et al. taught the successful use and delivery of melittin-PEI•DNA complexes *in vivo*.

Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of filing.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached from 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James “Doug” Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

May 20, 2009
/Terra Cotta Gibbs/